**IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**HUNTINGTON DIVISION**

JOHN DAVID BRUMFIELD,

Plaintiff,

v. CIVIL ACTION NO. 3:20-0522

MEDTRONIC, INC.,
MEDTRONIC USA, INC.,
MEDTRONIC PUERTO RICO OPERATIONS, CO., and
MEDTRONIC LOGISTICS, LLC,

Defendants.

**MEMORANDUM OPINION AND ORDER**

Pending before the Court is Defendants' Motion to Dismiss (ECF No. 9). For the following reasons, the Court **GRANTS IN PART** and **DENIES IN PART** the Motion.

## I. BACKGROUND

According to the Amended Complaint, Plaintiff John David Brumfield is a 70 year old man who has struggled with chronic lower back pain since 2000 due to three ruptured discs. After undergoing physical therapy, spinal cord stimulator implants, and a series of spinal injections, his doctors implanted Medtronic's SynchroMed II Infusion System ("SynchroMed II Device" or "Device") in his abdomen in 2012. The SynchroMed II Device is a programmable drug infusion system implanted in the body for drug delivery. The Device includes an infusion pump connected to a thin, flexible catheter attached to the intrathecal space (spinal canal) of the patient, into which the pump delivers medication (here, hydromorphone).

A few years after implantation, Plaintiff began to notice pain returning to his lower back. On or about September 2, 2018, Plaintiff visited the emergency room due to nausea, vomiting,

severe muscle and joint pain, chills, sweats, goosebumps, anxiety, and depression, and severe diarrhea. Plaintiff suspected that his symptoms were due to hydromorphone withdrawals, and his doctor recommended that the Device's pump be replaced. On September 24, 2018, Plaintiff underwent surgery to replace the pump. His surgeon wrote in a report that the "intrathecal pump was in a state of motor stall." Am. Compl. ¶ 19, ECF No. 3.

Plaintiff filed the Amended Complaint in this action against Medtronic on September 18, 2020. [1] He asserts five counts: (1) Strict Liability Manufacturing Defect; (2) Negligent Manufacturing Defect; (3) Breach of Implied Warranty of Merchantability and Fitness; (4) Fraudulent Misrepresentation; and (5) Punitive Damages. ECF No. 3. Plaintiff agreed to dismiss his Implied Warranty of Fitness for a Particular Purpose and Fraudulent Misrepresentation claims. Pl.'s Resp. 13, ECF No. 17. Each of the remaining counts arises from Plaintiff's claim that the motor stalled "as a direct result of Medtronic's violations of Federal law in that their manufacturing failures caused and allowed Mr. Brumfield's device to be manufactured defectively." Am. Compl. ¶ 94.

In support of this claim, Plaintiff alleges that FDA inspections and warnings indicate that Medtronic manufactured the Device in deviation of federal manufacturing requirements and reflect "the seriousness of Defendant's violations of federal law and negligence in the manufacture of the SynchroMed II Device." Am. Compl. ¶ 40. The Complaint details several warning letters, recalls, and lawsuits concerning the SynchroMed II Device and identifies those which may have affected Plaintiff's Device.

Medtronic now asks the Court to dismiss the suit on two grounds: (1) Plaintiff's claims are

[1] Defendants in this case, Medtronic, Inc., Medtronic Puerto Rico Operations, Inc., and Medtronic Logistics, LLC, are collectively referred to as "Medtronic" or "Defendants" in this Opinion.

preempted by the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act; and (2) the Complaint does not contain a plausible claim that entitles Plaintiff to relief. For the reasons stated below, the Court rejects both of these arguments.

## II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) authorizes courts to dismiss complaints that fail to state a claim upon which relief can be granted. To survive a Rule 12(b)(6) motion, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A motion to dismiss will be granted if, "after accepting all well-pleaded allegations in the plaintiff's complaint as true and drawing all reasonable factual inferences from those facts in the plaintiff's favor, it appears certain that the plaintiff cannot prove any set of facts in support of his claim entitling him to relief." *Edwards v. City of Goldsboro*, 178 F.3d 231, 244 (4th Cir. 1999).

## III. DISCUSSION

### (1) Preemption

#### a. Medical Device Amendments

Defendant first argues that Plaintiff has failed to demonstrate that he is entitled to relief because his claims are preempted. The Supremacy Clause invalidates or preempts any "state law that 'interferes with, or is contrary to' federal law." *Pinney v. Nokia, Inc.*, 402 F.3d 430, 453 (4th Cir. 2005) (quoting *Free v. Bland*, 369 U.S. 663, 666 (1962)). "Congress may indicate pre-emptive intent through a statute's express language or through its structure and purpose." *Raab v. Smith & Nephew, Inc.*, 150 F. Supp. 3d 671, 685 (S.D. W. Va. 2015) (citing *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008)). Defendant argues that Plaintiff's claims are expressly preempted by the Medical Device Amendments ("MDA").

In 1976, Congress passed the MDA and enacted a federal oversight scheme for medical devices. The extent of this oversight varies by device class. Class III devices are those which are "purported or represented to be for a use in supporting substantial importance in preventing impairment of human health," or "present[] a potential unreasonable risk of illness or injury." 21 USC § 360c(a)(1)(C)(ii). Class III devices must undergo the most extensive oversight, a process which the Supreme Court has described as "rigorous." *Riegel v. Medtronic, Inc*., 552 U.S. 312, 317 (2008). This premarket approval ("PMA") process requires device makers to submit applications that include comprehensive descriptions of a device's components, ingredients, and properties, as well as descriptions of manufacturing methods, facilities, and processes. *Id.* at 318 (quoting § 360e(c)(1)). Based on this information, the FDA may approve a device maker's application and issue a PMA approval order for the device. *Id*. (citing § 360e(d)). Manufacturers may not make changes to such devices unless they first seek and obtain permission from the FDA. *Id*. at 319.

Once a Class III device obtains the FDA's approval, the device maker must adhere to Current Good Manufacturing Practices ("CGMPs") promulgated by the FDA. 21 C.F.R. § 820.1. The CGMP regulations serve to "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." 21 C.F.R. § 820.1(a)(1). "To comply with CGMP requirements, a device manufacturer must adopt a variety of procedures and controls relating to areas such as: (1) design control, (2) quality assurance, (3) manufacturing and processing, (4) process validation, (5) device inspection, and (6) corrective and preventive action." *Id*. at §§ 820.1-.250. Any device not made in conformity with the CGMP requirements is considered "adulterated." *Id*. at § 351(h). The FDCA expressly prohibits "[t]he introduction . . . into interstate commerce of any food, drug,

device, tobacco product, or cosmetic that is adulterated or misbranded." *Id*. at § 331(a).

In light of this oversight scheme, Congress invalidated all state requirements "different from, or in addition to, any requirement applicable under [the Federal Food, Drug, and Cosmetic Act]." *Id*. at § 360k(a)(1). In *Riegel*, the Supreme Court extended this rule to state common law tort claims and created a two-step analysis for determining whether a plaintiff's claims are preempted. *See Riegel*, 552 U.S. at 321-22. Under the first step, courts must determine whether the device at issue is subject to federal statutory requirements. *See id*. It is undisputed that the SynchroMed II Device is a Class III medical device subject to the MDA, and that it received premarket approval. Consequently, this Court's analysis will focus on the second step.

Under the second step, the court must consider whether the claims attempt to impose state safety and effectiveness requirements that are "different from, or in addition to," federal requirements. *See id*. at 328. Although considered a "narrow exception," *Riegel* held that a claim does not impose a requirement "different from, or in addition to" federal law if it is "premised on a violation of FDA regulations." *Riegel*, 552 U.S. at 330 (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996). The Fourth Circuit has not considered whether a claim is "parallel" if it alleges that a Class III device maker is liable for manufacturing defects caused by violations of federal manufacturing regulations. However, several other courts, including the Southern District of West Virginia and the Fifth, Sixth, Seventh, and Eleventh circuits, have held that § 360k does not preempt such claims. *See, e.g.*, *Raab*, 150 F. Supp. 3d at 692 (S.D. W. Va.) (Johnston, C.J.); *Bass v. Stryker Corp*., 669 F.3d 501, 511-12 (5th Cir. 2012); *Howard v. Sulzer Orthopedics, Inc*., 382 Fed. Appx. 436 (6th Cir. 2010); *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010); *Godelia v. Doe 1*, 881 F.3d 1309 (11th Cir. 2018).

Although there has been some debate about exactly which federal manufacturing

requirements may predicate parallel claims, this Court is persuaded by the decisions permitting claims premised on PMA and CGMP requirements. *Compare Bausch*, 630 F.3d at 555 (holding that claims premised on Quality System Regulations and Current Good Manufacturing Process requirements are not preempted); *with In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litig.*, 592 F.Supp.2d 1147, 1157 (D. Minn. 2009) (finding plaintiff's claims were "simply too generic, standing alone" to serve as basis for manufacturing-defect claim), aff'd, 623 F.3d 1200 (8th Cir. 2010). As noted in these decisions, the text of § 360k indicates that parallel claims may be predicated on "any requirement applicable under this chapter to the device." 21 U.S.C. § 360k(a); *see, e.g.*, *Bausch*, 630 F.3d at 555. The Supreme Court has noted that this rule extends to FDA regulations promulgated under the MDA. *Riegel*, 552 U.S. at 330 (citing *Lohr*, 518 U.S. at 495).

Compliance with PMA specifications and CGMPs is required by the MDA and FDA regulations. Under 21 C.F.R. § 814.80, a device may not be manufactured "in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." Therefore, liability based on a deviation from these FDA-approved formal specifications does not impose requirements "different from, or in addition to," federal law. Likewise, claims premised on CGMP regulations do not impose requirements "different from, or in addition to," federal law because those regulations apply to Class III device manufacturers. *Bausch*, 630 F.3d at 556 (citing 21 C.F.R. §§ 820.72 to 820.90). Accordingly, to the extent that Plaintiff has alleged a manufacturing defect evidenced by deviations from PMA specifications and CGMPs, this Court will find that his claims are not preempted.

**b. Plaintiff's Claims**

Here, Plaintiff alleges two manufacturing defect claims (strict liability and negligence) and

one breach of implied warranty claim.[2] Each claim is premised on the following allegations: that Medtronic manufactured the SynchroMed II Device implanted in Plaintiff's abdomen; that Medtronic's manufacturing practices deviated from the specifications set out in the applicable PMA and CGMPs; that these deviations caused the Device to be manufactured defectively; and that the defective Device's motor stalled and failed to deliver medication as programmed, causing Plaintiff to suffer withdrawal symptoms and other injuries. Given that these allegations are rooted in PMA and CGMP requirements, Plaintiff's claims are not preempted.

This holding is consistent with other decisions involving the SynchroMed II Device. For example, in *Sullivan* the plaintiff brought claims nearly identical to Brumfield's. *See Sullivan v. Medtronic, Inc*., No. 4:20 CV 344 CDP, 2020 WL 6381819, at *6 (E.D. Mo. Oct. 30, 2020). There, the plaintiff alleged that Medtronic defectively manufactured Sullivan's SynchroMed II Device (the same model as Plaintiff's) in deviation from the PMA specifications and CGMPs; and that defect caused the motor to stall. *Id*. Medtronic moved to dismiss Sullivan's claims and argued that they were preempted. *Id*. at 1. The district court denied Medtronic's motion and held that Sullivan's state law claims (the same three as Plaintiff's) were not preempted. *Id*. at 4-7. The court in *Bledsoe v. Medtronic, Inc.* reached the same conclusion when faced with the same manufacturing defect claims based on the SynchroMed II Device's motor stalling. *Bledsoe v. Medtronic, Inc.*, No. 2:18-CV-133-TLS, 2020 WL 43107, at *7 (N.D. Ind. Jan. 3, 2020).

Here, as in these other cases, Medtronic argues that Plaintiff's claims are preempted

[2] The parties agree that all three claims rise or fall together for the purposes of preemption and plausibility. Accordingly, this Court will analyze these claims together. *See Raab*, 159 F. Supp. 3d at 700 ("Under West Virginia law, claims for strict liability and breach of the implied warranty of merchantability are coextensive in products liability.") (citing *Keffer v. Wyeth*, 791 F.Supp.2d 539, 542 (S.D. W.Va. 2011)) (internal quotations omitted).

because his allegations raise design defect rather than manufacturing defect claims: "Plaintiff attempts to hold Medtronic accountable for not ensuring Plaintiff received a ***later version*** of the SynchroMed® II device that contained ***additional design features*** that may have prevented his device from allegedly stalling when it did." Defs.' Reply at 6, ECF No. 20 (emphasis in original). Although claims challenging an FDA-approved design may be preempted, Plaintiff's Complaint makes plain that he is alleging a manufacturing defect. Medtronic may ultimately prevail on this defense after discovery; however, at the motion to dismiss stage the Court cannot ignore Plaintiff's allegations. As such, these arguments are an inappropriate basis for dismissal.

Defendant next argues that Plaintiff's state law claims are preempted because West Virginia's products liability standards exceed federal requirements. In West Virginia, "the general test for establishing strict liability in tort is whether the involved product is defective in the sense that it is not reasonably safe for its intended use." Syl. Pt. 4, *Morningstar v. Black and Decker Mfg. Co*., 253 S.E.2d 666 (W. Va. 1979). From this general standard, West Virginia recognizes "three broad, and not necessarily mutually exclusive, categories: design defectiveness; structural defectiveness; and use defectiveness arising out of the lack of, or the inadequacy of, warnings, instructions and labels." *Id*. For structural or manufacturing claims, the inquiry "centers on the physical condition of the product which renders it unsafe when the product is used in a reasonably intended manner." *Id*. at 683. "The term "unsafe" imparts a standard that the product is to be tested by what the reasonably prudent manufacturer would accomplish in regard to the safety of the product . . . at the time the product was made." *Id*.

Defendant argues that the "reasonably prudent manufacturer" standard would permit a jury to impose liability for conduct even if it is consistent with federal regulations. The Court agrees

that this standard is potentially too broad for the purposes of § 360k.[3] Nevertheless, Plaintiff's claims are sufficiently narrow to avoid preemption at this stage. As described above, Plaintiff has premised his manufacturing defect allegations on the PMA and CGMP requirements. Therefore, Defendant's concerns regarding West Virginia's generic standard for products liability do not warrant dismissal.

In sum, Plaintiff's manufacturing defect and breach of implied warranty claims are not preempted to the extent that he has premised the claims on violations of federal requirements, specifically the PMA and CGMPs. Therefore, the Court rejects Defendants' first argument for dismissal.

**(2) Failure to Plead a Plausible Claim**

Defendants' second argument for dismissal is that the Complaint does not satisfy the well-pleaded complaint rule under Federal Rule of Civil Procedure 8. Under Rule 8(a)(2), a complaint "requires only a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555 (citing *Conley v. Gibson*, 355 U.S. 41, 47 (1957)) (quotations and alterations omitted). "There are no special pleading requirements for product liability claims in general," but courts have recognized that plaintiff's pleading burden must "be commensurate

[3] The Court notes, however, that the manufacturing defect standard under the West Virginia's Pattern Jury Instructions is likely not too broad for the purposes of § 360k. To demonstrate that the plaintiff is entitled to relief, the plaintiff must prove: (1) that defendant made the product; and (2) that the product contained a manufacturing defect when it left defendant's possession; and (3) that as a result of the defect, the product was not reasonably safe for its intended use; and (4) that plaintiff was injured while using the product in a reasonably foreseeable way; and (5) that the product's defect was a proximate cause of plaintiff's injury. W.V. Pattern Jury Instr. Civil. § 412.

The pattern instructions define "manufacturing defect" as follows: "A product contains a manufacturing defect if the product differs from the manufacturer's design or specifications or from other typical units of the same product line." W.V. Pattern Jury Instr. Civil. § 413.

with the amount of information available to them." *Bausch*, 630 F.3d at 561 (quoting *In re Medtronic*, 623 F.3d at 1212 (Melloy, J., dissenting)).

In *Bausch*, the Seventh Circuit held that the plaintiff sufficiently pleaded a manufacturing defect claim with the following allegations: (1) that the defendant manufactured the hip replacement system she received; (2) that the product was a Class III medical device subject to the authority of the FDA; (3) that the product was unreasonably dangerous, causing plaintiff to suffer; and (4) that defendants knew that the product was defective because defendants had received several complaints from patients and notice from the FDA that the products were adulterated. *Bausch*, 630 F.3d at 558-59. In so holding, the court noted that plaintiffs need not identify the specific defect in the complaint because such specificity is often not possible before discovery. *Id*.

Likewise, in *Raab*, Chief Judge Johnston held that the plaintiff sufficiently pleaded a strict products liability claim based on noncompliance with CGMP requirements by identifying the medical device component that failed, and "most importantly," citing several violations of federal law that "suggeste[ed] a defect in the [device's] manufacture[]." *Raab*, 150 F. Supp. 3d at 694. He concluded that the plaintiff plausibly tied these violations to her own device because her allegations described similar malfunctioning. *Id*.

Here, as in *Bausch* and *Raab*, Plaintiff has alleged his claims with enough specificity to state a plausible claim and provide Medtronic sufficient notice. The Amended Complaint includes specific allegations as to the device (SynchroMed II Device, model number 8637-40, serial number NGV468109H) and malfunction (motor stall due to motor corrosion). Although this alone does not establish that the defect was caused by the Device's manufacture and not design, Plaintiff has proffered several FDA warning letters that support a plausible inference that the cause was manufacturing.

For example, in 2009, an FDA inspection "revealed that the Synchromed® II Pumps are adulterated within the meaning of [21 U.S.C. §351(h)]." Ex. 4 to Compl., ECF No. 1-4. Specifically, the FDA found that "multiple Synchromed® II Pumps were released for distribution and implanted in patients even though they were not filled with propellant as required by Medtronic's Process Operation Description." *Id*. Another pump was "found that did not show evidence of a perforated septum." *Id*. The Warning Letter concluded that these violations "may be symptomatic of serious problems in [Medtronic's] manufacturing quality assurance systems." *Id*.

In 2012, the same year Plaintiff's Device was implanted, the FDA performed an inspection and again found that the "Synchromed® II Pumps are adulterated within the meaning of . . . 21 U.S.C. § 351(h)." Ex. 6 to Compl., ECF No. 1-6. The FDA outlined specific deviations from regulations, including its finding that Medtronic failed to establish procedures to prevent the recurrence of "motor corrosion resulting in device failure (motor stall)," an issue that surfaced in 2007 and involved 567 complainants. *Id.* Even after having the opportunity to respond, the FDA found that Medtronic's corrective actions were insufficient and predicted additional patient injuries resulting from motor corrosion. The FDA concluded that Medtronic's failure to adopt appropriate corrective and protective actions violated 21 C.F.R. § 820.100(a).

According to Medtronic, Plaintiff has failed to link these FDA documents to Plaintiff's specific device. The Court disagrees. Plaintiff alleges that, "during the time Plaintiff's SynchroMed II Device was being manufactured by Medtronic, the FDA conducted numerous inspections of Medtronic's manufacturing and quality control facilities . . . discovering a multitude of significant violations of federal law . . . . " Am. Compl. ¶ 41. This allegation is plausible given the proximity in time between Plaintiff's surgery and the FDA's 2012 inspection. It is also plausible because at least one of the warning letters discussed the same type of malfunction (motor

stall) and suggested that Medtronic had notice of this issue since 2007 but had failed to correct it. Given that the FDA has significantly redacted the warning letters and does not specify which devices were adulterated by model or serial number, requiring Plaintiff to directly tie his Device to the letters would be unreasonable. Accordingly, the Court finds that these allegations are commensurate with the information available to Plaintiff and support a plausible claim.

The Court rejects Medtronic's final argument for similar reasons. Medtronic argues that Plaintiff failed to allege how his Device deviated from the PMA requirements. However, the Court finds that PMA-specific allegations are not required to give Defendants adequate notice. Plaintiff has provided his Device's model and serial number, identified the specific malfunction (motor stall), and alleged a cause of the malfunction (motor corrosion). These allegations give Medtronic—which, unlike Plaintiff, has access to the unredacted warning letters and PMA—adequate notice of the nature and scope of Plaintiff's claims. To hold otherwise would risk imposing an impossible pleading standard, given that the PMA and Medtronic's manufacturing practices may not be available to plaintiffs before discovery. *See* 21 C.F.R. § 814.9; *Bausch*, 630 F.3d at 558 (7th Cir. 2010) ("Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim."). Thus, the Court rejects Defendants' argument and concludes that dismissal is unwarranted.

## IV. CONCLUSION

For the previously stated reasons, the Court **GRANTS IN PART** and **DENIES IN PART** the Motion to Dismiss (ECF No. 9). Count IV of the Amended Complaint is **DISMISSED**.

The Clerk is **DIRECTED** to send a copy of this Order to counsel of record and any unrepresented parties.

ENTER: March 11, 2021

ROBERT C. CHAMBERS
UNITED STATES DISTRICT JUDGE